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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,809	12/16/2003	Jay Miazga	000309-00259	2862

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BLANK ROME LLP
600 NEW HAMPSHIRE AVENUE, N.W.
WASHINGTON, DC 20037

EXAMINER	
JOHNSON, SHEVON ELIZABETH	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,809	MIAZGA ET AL.	
	Examiner	Art Unit	
	Shevon E. Johnson	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/16/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *6,7,12-20 and 35-39* is/are allowed.

6)☒ Claim(s) *1,2,5,8,10,21-24,27,29,30 and 32* is/are rejected.

7)☒ Claim(s) *3,9,11,25,26,28,31,33 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Drawings

1. Figures 1-28 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the percutaneous probe with non-linear shape as claimed in claim 6 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 5, 8, 10, 21-24, 27, 29, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodicky et al. (U.S. Patent No. 4,895,147).

In regards to claim 1, Bodicky discloses an apparatus for percutaneous application, comprising: a housing 12; a percutaneous probe 74 having a sharp end and being positioned within the housing, the percutaneous probe movable relative to the housing between a stowed position and at least one of a first deployed position and a second deployed position, with the percutaneous probe projecting from the housing by a first distance when in the first deployed position, and with the percutaneous probe projecting from the housing by a second distance greater than the first distance when in the second deployed position; and a depth control device operatively coupled to the percutaneous probe, the depth control device 13 having a first configuration to allow the percutaneous probe to be moved to the first deployed position, the depth control device having a second configuration to allow the percutaneous probe to be moved to the second deployed position (col. 3, line 11- col. 4, line 38; fig. 1).

In regards to claim 2, Bodicky discloses an apparatus wherein the depth control device includes a pre-adjustable portion 13 configured to be movable between a first stop position and a second stop position without moving the percutaneous probe 74, and wherein the percutaneous probe is movable to the first deployed position when the pre-adjustable portion is in the first stop position, the percutaneous probe movable to the second deployed position when the pre-adjustable portion is in the second stop position (col. 3, line 54-64; col. 4, lines 17-24; fig. 1).

In regards to claim 5, Bodicky discloses an apparatus comprising a locking device 84 positioned to selectively restrict motion of the percutaneous probe when the percutaneous probe is in at least one of the stowed position, the first deployed position and the second deployed position (col. 3, line 11- col. 4, line 38; fig. 1).

In regards to claim 8, Bodicky discloses an apparatus for percutaneous application, comprising: a housing 12; a first percutaneous probe 74 positioned within the housing, the first percutaneous probe having a sharp end and a first percutaneous length, the first percutaneous probe movable relative to the housing between a first stowed position and a first deployed position; and a second percutaneous probe

positioned within the housing simultaneously with the first percutaneous probe, the second percutaneous probe having a sharpened end and a second percutaneous length, the second percutaneous probe movable relative to the housing between a second stowed position and a second deployed position (col. 3, line 11- col. 4, line 38; fig. 1).

In regards to claim 10, Bodicky, discloses an apparatus for percutaneous application, comprising: a housing 12; a percutaneous probe 74 having a sharp end and disposed within the housing, the percutaneous probe being movable relative to the housing between a stowed position and at least one of a first deployed position and a second deployed position, the percutaneous probe having a first deployed length external to the housing when in the first deployed position, the percutaneous probe having a second deployed length external to the housing when in the second deployed position; and a tool movable 48 relative to the housing, the tool having an engaging portion positioned to selectively engage the percutaneous probe at a first axial location to move the percutaneous probe to the first deployed position, the engaging portion positioned to selectively engage the percutaneous probe at a second axial location spaced apart from the first axial location to move the percutaneous probe to the second deployed position (col. 3, line 11- col. 4, line 38).

In regards to claim 21, Bodicky discloses an apparatus for percutaneous application, comprising: a housing having an attachment device configured to be releasably attached to a recipient's skin, the housing further having an external housing surface extending away from the attachment device and facing outwardly transverse to the attachment device; a percutaneous probe having a sharp end and disposed within the housing, the percutaneous probe movable relative to the housing between a stowed position and at least one deployed position; an actuator movably disposed within the housing, the actuator carrying the percutaneous probe and having a receiving portion; and an actuator tool 48 having an engaging portion positioned to releasably engage the receiving portion of the actuator, the actuator being movable between a first position and a second position, with the percutaneous probe in its stowed position when the actuator tool is in its first position and with the percutaneous probe in its deployed position when the actuator tool is in its second position, and wherein at least a portion of the housing surface is exposed when the actuator tool is in the first position and covered by the actuator tool when the actuator tool is in the second position (col. 3, line 11- col. 4, line 38).

In regards to claim 22, Bodicky discloses an apparatus wherein the housing includes an exit portion through which the percutaneous probe extends when in the deployed position, and wherein the

surface of the housing faces transverse to the exit portion, further, wherein the actuator tool includes a grip portion 48 configured to receive an operator's hand, and wherein the grip portion is positioned adjacent to the surface of the housing when the actuator tool is in the second position (col. 3, line 11- col. 4, line 38).

In regards to claims 23, 24, 27, 29, 30 and 32, Bodicky discloses a method for operating a percutaneous probe apparatus, comprising: choosing a selected deployment depth from at least a first deployment depth and a second deployment depth; deploying the percutaneous probe to the selected deployment depth in a recipient's tissue; halting deployment of the percutaneous probe at the selected deployment depth with a depth control device of the percutaneous probe apparatus having one of at least two configurations; withdrawing the percutaneous probe from the recipient's tissue; and stowing the percutaneous probe in the housing (col. 3, line 11- col. 4, line 38).

5. Claims 1, 2, 5, 8, 10, 21-24, 27, 29, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Harding (U.S. Patent No. 5,613,978).

In regards to claim 1, Harding discloses an apparatus for percutaneous application, comprising: a housing 10; a percutaneous probe 72 having a sharp end and being positioned within the housing, the percutaneous probe movable relative to the housing between a stowed position and at least one of a first deployed position and a second deployed position, with the percutaneous probe projecting from the housing by a first distance when in the first deployed position, and with the percutaneous probe projecting from the housing by a second distance greater than the first distance when in the second deployed position; and a depth control device operatively coupled to the percutaneous probe, the depth control device 20 having a first configuration to allow the percutaneous probe to be moved to the first deployed position, the depth control device having a second configuration to allow the percutaneous probe to be moved to the second deployed position (col. 2, line 49 – col. 3, line 1; figs. 1-3).

In regards to claim 2, Harding discloses an apparatus wherein the depth control device includes a pre-adjustable portion configured to be movable between a first stop position and a second stop position without moving the percutaneous probe, and wherein the percutaneous probe is movable to the first deployed position when the pre-adjustable portion is in the first stop position, the percutaneous probe movable to the second deployed position when the pre-adjustable portion is in the second stop position. (col. 2, line 49 – col. 3, line 1).

In regards to claim 5, Harding discloses an apparatus comprising a locking device 13 positioned to selectively restrict motion of the percutaneous probe when the percutaneous probe is in at least one of the stowed position, the first deployed position and the second deployed position (col. 2, line 49 – col. 3, line 1).

In regards to claim 8, Harding discloses an apparatus for percutaneous application, comprising: a housing 10; a first percutaneous probe 72 positioned within the housing, the first percutaneous probe having a sharp end and a first percutaneous length, the first percutaneous probe movable relative to the housing between a first stowed position and a first deployed position; and a second percutaneous probe positioned within the housing simultaneously with the first percutaneous probe, the second percutaneous probe having a sharpened end and a second percutaneous length, the second percutaneous probe movable relative to the housing between a second stowed position and a second deployed position (col. 2, line 49 – col. 3, line 1).

In regards to claim 10, Harding discloses an apparatus for percutaneous application, comprising: a housing 10; a percutaneous probe 72 having a sharp end and disposed within the housing, the percutaneous probe being movable relative to the housing between a stowed position and at least one of a first deployed position and a second deployed position, the percutaneous probe having a first deployed length external to the housing when in the first deployed position, the percutaneous probe having a second deployed length external to the housing when in the second deployed position; and a tool movable 13 relative to the housing, the tool having an engaging portion positioned to selectively engage the percutaneous probe at a first axial location to move the percutaneous probe to the first deployed position, the engaging portion positioned to selectively engage the percutaneous probe at a second axial location spaced apart from the first axial location to move the percutaneous probe to the second deployed position (col. 2, line 49 – col. 3, line 1).

In regards to claims 23, 24, 27, 29, 30 and 32, Harding discloses a method for operating a percutaneous probe apparatus, comprising: choosing a selected deployment depth from at least a first deployment depth and a second deployment depth; deploying the percutaneous probe to the selected deployment depth in a recipient's tissue; halting deployment of the percutaneous probe at the selected deployment depth with a depth control device of the percutaneous probe apparatus having one of at least two configurations; withdrawing the percutaneous probe from the recipient's tissue; and stowing the percutaneous probe in the housing (col. 2, line 49 – col. 3, line 1).

6. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Rutynowski et al. (U.S. Patent No. 6,613,064).

In regards to claim 1, Rutynowski discloses an apparatus for percutaneous application, comprising: a housing 1; a percutaneous probe 8 having a sharp end and being positioned within the housing, the percutaneous probe movable relative to the housing between a stowed position and at least one of a first deployed position and a second deployed position, with the percutaneous probe projecting from the housing by a first distance when in the first deployed position, and with the percutaneous probe projecting from the housing by a second distance greater than the first distance when in the second deployed position; and a depth control device operatively coupled to the percutaneous probe, the depth control device 3 having a first configuration to allow the percutaneous probe to be moved to the first deployed position, the depth control device having a second configuration to allow the percutaneous probe to be moved to the second deployed position (col. 1, line 51 – col. 2, line 36; figs. 1-4).

In regards to claim 8, Rutynowski discloses an apparatus for percutaneous application, comprising: a housing; a first percutaneous probe positioned within the housing, the first percutaneous probe having a sharp end and a first percutaneous length, the first percutaneous probe movable relative to the housing between a first stowed position and a first deployed position; and a second percutaneous probe positioned within the housing simultaneously with the first percutaneous probe, the second percutaneous probe having a sharpened end and a second percutaneous length, the second percutaneous probe movable relative to the housing between a second stowed position and a second deployed position (col. 1, line 51 – col. 2, line 36).

7. Claims 1, 2, 4 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Roe (U.S. Patent No. 6,645,219).

In regards to claim 1, Roe discloses an apparatus for percutaneous application, comprising: a housing 10; a percutaneous probe L having a sharp end and being positioned within the housing, the percutaneous probe movable relative to the housing between a stowed position and at least one of a first deployed position and a second deployed position, with the percutaneous probe projecting from the housing by a first distance when in the first deployed position, and with the percutaneous probe projecting from the housing by a second distance greater than the first distance when in the second deployed position; and a depth control device operatively coupled to the percutaneous probe, the depth control

device 1 having a first configuration to allow the percutaneous probe to be moved to the first deployed position, the depth control device having a second configuration to allow the percutaneous probe to be moved to the second deployed position (col. 6, line 28 – col. 8, line 28; figs. 1-3B).

In regards to claim 2, Roe discloses an apparatus wherein the depth control device includes a pre-adjustable portion configured to be movable between a first stop position and a second stop position without moving the percutaneous probe, and wherein the percutaneous probe is movable to the first deployed position when the pre-adjustable portion is in the first stop position, the percutaneous probe movable to the second deployed position when the pre-adjustable portion is in the second stop position (col. 6, line 28 – col. 8, line 28).

In regards to claim 4, Roe discloses an apparatus comprising an actuator carrying the percutaneous probe, the actuator being rotatably supported by the housing, the actuator rotatable between a first position with the percutaneous probe in the first deployed position and a second position rotationally spaced apart from the first position with the percutaneous probe in the second deployed position (col. 6, line 28 – col. 8, line 28).

In regards to claim 8, Roe discloses an apparatus for percutaneous application, comprising: a housing; a first percutaneous probe positioned within the housing, the first percutaneous probe having a sharp end and a first percutaneous length, the first percutaneous probe movable relative to the housing between a first stowed position and a first deployed position; and a second percutaneous probe positioned within the housing simultaneously with the first percutaneous probe, the second percutaneous probe having a sharpened end and a second percutaneous length, the second percutaneous probe movable relative to the housing between a second stowed position and a second deployed position (col. 6, line 28 – col. 8, line 28).

Allowable Subject Matter

8. Claims 6, 7, 12-20 and 35-39 are allowed. Claims 3, 9, 11, 25, 26, 28, 31, 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shevon Johnson
Art Unit 3766

Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766